In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 26, 2025

CHRISTINA MITCHELL, **PUBLISHED**

Petitioner, No. 19-1534V

Special Master Nora Beth Dorsey v.

SECRETARY OF HEALTH Decision Awarding Damages; Influenza AND HUMAN SERVICES,

("Flu") Vaccine; Immune

Thrombocytopenia Purpura ("ITP"); Pain

Respondent. and Suffering; Lost Wages; Unreimbursable

Expenses.

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner. Adam Nemeth Muffett, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON DAMAGES¹

On October 2, 2019, Christina Mitchell ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2018).² Petitioner alleges that she suffered chronic immune thrombocytopenia purpura ("ITP") as the result of an influenza ("flu") vaccination administered on October 9, 2016. Petition at Preamble (ECF No. 1). On January 11, 2023, the undersigned

¹ Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Ruling will be available to anyone with access to the Internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018). All citations in this Ruling to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

issued a Ruling on Entitlement, finding that Petitioner was entitled to compensation. Ruling on Entitlement dated January 11, 2023 (ECF No. 78).

The parties were unable to resolve damages and requested that the Court enter a schedule for damages briefs. Since then, the parties' briefs have been filed.

I. PROCEDURAL HISTORY

Petitioner filed her petition on October 2, 2019. Petition. The early procedural history from October 2019 through 2022 was set forth in the undersigned's Ruling on Entitlement and will not be repeated here. See Ruling on Entitlement at 5.

Thereafter, the parties engaged in settlement discussions but were not able to resolve this matter informally and requested to submit the damages items that remained in dispute to the Court's resolution by briefing. See Petitioner's ("Pet.") Status Report ("Rept."), filed Feb. 16, 2024 (ECF No. 115); Joint Status Rept., filed Mar. 18, 2024 (ECF No. 117). During settlement discussions, Petitioner filed various records, including updated medical records, expert reports, and an affidavit, and Respondent filed expert reports. Pet. Exhibits ("Exs.") 36-53; Resp. Exs. CC-DD.

On June 3, 2024, Petitioner filed a brief in support of her claim for damages. Pet. Brief in Support of Damages ("Pet. Br."), filed June 3, 2024 (ECF No. 122). Respondent filed his responsive brief on July 18, 2024. Respondent's Response to Pet. Br. ("Resp. Br."), filed July 18, 2024 (ECF No. 126). Petitioner filed a reply on August 1, 2024. Pet. Reply Br. in Support of Damages ("Pet. Reply Br."), filed Aug. 1, 2024 (ECF No. 128).

This matter is now ripe for adjudication.

II. **FACTUAL HISTORY**

A. **Medical Record History**

The Ruling on Entitlement issued on January 11, 2023, and it set forth a summary of Petitioner's medical records and affidavits. See Ruling on Entitlement at 6-12. Further, the parties have set forth summaries of relevant facts which support their respective positions in their briefs, which the undersigned has reviewed as well as all of the medical records and evidence filed in this matter.

A brief summary of some facts relevant to this Decision follows. While all the records are important, these entries provide specific information about Petitioner's condition important to the undersigned's Ruling.

Prior to the vaccination at issue, Petitioner had a medical history that included annual examinations, acute pharyngitis, acute bronchitis, strep throat, and upper respiratory infections. Pet. Ex. 8 at 2-13; Pet. Ex. 9 at 1-7. On September 12, 2013, Petitioner went in for an annual

appointment with her OB/GYN. Pet. Ex. 12 at 6. At this appointment, her platelet count was below normal at 137,000 (range 155,000-379,000). Id. at 7.

On October 9, 2016, Petitioner received a flu vaccination. Pet. Ex. 1 at 3. On October 21, 2016, Petitioner saw her OB/GYN for her annual visit. Pet. Ex. 3 at 11-12. Petitioner reported she felt dizzy during her menstrual period and headaches the week prior. Id. She reported no other abnormalities during this appointment. Id.

Petitioner had an appointment on December 7, 2016 with her OB/GYN due to a prolonged, heavy period. Pet. Ex. 3 at 8. She reported heavy bleeding for eight days, passing clots, and feeling dizzy. Id. Nurse Practitioner, Elizabeth Newsome, performed a general examination and noted no abnormalities. Id. Blood work was ordered. Id. The following day, on December 8, 2016, Petitioner's lab results came back showing a platelet count of 12,000 (range 150,000-400,000). Id. at 13-14. Petitioner was advised her platelet count was critically low and she needed to see a hematologist immediately. Id. at 13.

Dr. Gautam Kishore Kale, a hematologist-oncologist, evaluated Petitioner on December 12, 2016. Pet. Ex. 4 at 5. Dr. Kale diagnosed Petitioner with "[s]evere thrombocytopenia likely immune thrombocytopenia versus thrombocytopenia due to recent upper respiratory tract infection." Id. at 12. He noted that her ITP "[c]ould be from an acute viral upper respiratory infection which hopefully will improve over time and not cause chronic ITP." Id. During this appointment, Petitioner also complained of increased clumsiness and cognitive slowing. Id. Dr. Kale sent Petitioner for a computerized tomography ("CT") that showed no evidence of bleeding, however there was a 12 mm area of high density that Dr. Kale postulated was calcium or a meningioma.³ Id. at 12, 24. He did not find it to be of concern and determined her symptoms could be from her upper respiratory infection. Id. An ultrasound of her abdomen showed increased spleen size. Id. at 12. Petitioner was prescribed prednisone⁴ to increase her platelet count. Id.

On December 19, 2016, Petitioner was seen for a follow up appointment. Pet. Ex. 4 at 18. Her platelet count had increased to 126,000. Id. at 24. Dr. Kale's assessment was again "severe thrombocytopenia likely immune thrombocytopenia versus thrombocytopenia due to recent viral upper respiratory tract infection." Id. He decided to taper her prednisone and monitor her platelet count weekly with the hope that her ITP was not chronic and would improve over time. Id. at 25.

³ Meningioma is "a benign, slow-growing tumor of the meninges." Meningioma, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=30336 (last visited Feb. 11, 2025).

⁴ Prednisone is "a synthetic glucocorticoid derived from cortisone, administered orally as an antiinflammatory and immunosuppressant in a wide variety of disorders." Prednisone, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=40742 (last visited Feb. 11, 2025).

After beginning the taper, Petitioner was seen for a follow up visit on December 27, 2016. Pet. Ex. 4 at 27, 30. Her platelet count had dropped to 32,000. Id. at 30, 33. Dr. Kale increased her prednisone to 40 mg per day. Id. at 34.

On January 3, 2017, Petitioner was seen for another follow up appointment. Pet. Ex. 4 at 35. Her platelet count was stable at 42,000 on 40 mg of prednisone. <u>Id.</u> at 38, 42. Based on this, Dr. Kale opined that Petitioner's thrombocytopenia appeared to be steroid dependent. Id. at 42. Dr. Kale and Petitioner discussed other treatment options including high dose dexamethasone⁵ and a slow prednisone taper, Rituxan, or a splenectomy. Detitioner wanted to stop taking steroids because of her "sense of anxiety" and they made her feel "a little edgy" and gain weight. Id. at 38, 42. She also indicated she did not want a splenectomy at this time. Id. at 38. Petitioner decided to consider these options and continue taking prednisone. Id. at 42. On January 10, 2017, Petitioner was seen for another follow up appointment. Id. at 45. Petitioner had decided to start Rituxan and continue taking prednisone until Rituxan became effective. Id. at 51.

Petitioner was seen again on February 6, 2017. Pet. Ex. 4 at 53. Her diagnosis was "isolated thrombocytopenia likely ITP." Id. at 56. Petitioner was tapering off prednisone and was taking 30 mg and reducing by five mg every five to seven days. Id. She had received three of her four doses of Rituxan and was receiving her final dose that day. Id. She indicated that "she did not fill her prescription for lorazepam[,] which was ordered for anxiety/insomnia." Id. at 57. Her platelet count had dropped to 11,000 the previous week, on January 30, 2017. Id. at 57-59. She had then received high dose dexamethasone and her platelet count had increased to 183,000 on February 6. Id. She had another follow up appointment on February 13, 2017. Id. at 62. After tapering her prednisone to 20 mg per day, Petitioner's platelet count dropped to 9,000 and she experienced epistaxis (nosebleed). Id. at 67-68. Her prednisone was increased to 60 mg

⁵ Dexamethasone is administered as "an antiinflammatory and immunosuppressant in a wide variety of disorders." Dexamethasone, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=13599 (last visited Feb. 11, 2025).

⁶ Rituxan is used "in the treatment of CD20-positive, B-cell non-Hodgkin lymphoma; administered intravenously." Rituximab, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=43977 (last visited Feb. 11, 2025).

⁷ Splenectomy is the "excision . . . of the spleen." Splenectomy, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=46675 (last visited on Feb. 11, 2025).

per day. Id. at 69. She agreed to be admitted to the hospital for intravenous immune globulin ("IVIG")⁸ and to start Nplate.⁹ Id.

The next follow up appointment was March 1, 2017. Pet. Ex. 4 at 71. Petitioner had responded well to IVIG and Nplate. Id. at 77. Her platelet count was up to 191,000. Id. Dr. Kale explained to Petitioner that IVIG may remain effective for two-to-four weeks and since she was two weeks post-treatment, he would continue to monitor her platelets closely. Id. at 77-78. Dr. Kale tapered Petitioner's prednisone to 15 mg a day and then recommended continuing the taper with 10 mg per day for one week before stopping completely. Id. at 78. Dr. Kale's assessment at that visit was "severe labile immune thrombocytopenia (ITP)." Id. at 77.

Petitioner was seen for another follow up on March 15, 2017. Pet. Ex. 4 at 79. Petitioner was down to 10 mg of prednisone and received Nplate 2 mcg/kg. Id. at 85. By her appointment on March 30, 2017, Petitioner was off prednisone and her platelet count was at 101,000. Id. at 95. Petitioner continued to receive weekly Nplate treatments. Id. Again, Dr. Kale's diagnosis was "severe labile immune thrombocytopenia (ITP)." Id.

From April 2017 to July 2017, Petitioner's platelet counts remained stable. Pet. Ex. 4 at 97-130. On August 10, 2017, her platelet count decreased to 50,000 "in the setting of an [upper respiratory tract infection." Id. at 134, 136-37. On October 17, 2017, Petitioner was seen by Dr. Alice De-Ling Ma, a hematologist at UNC Healthcare, "for a second opinion regarding therapy for chronic ITP." Pet. Ex. 6 at 8. Dr. Ma recommended either a splenectomy or Rituxan. Id. at 9. On October 19, 2017, Petitioner returned to Dr. Kale and discussed similar treatment options. Pet. Ex. 4 at 146. Petitioner decided she wanted to switch to Promacta¹⁰ with Nplate as a backup if her platelet count dropped below 50,000. Id. She decided against splenectomy. Pet. Ex. 37 at 6.

Petitioner's diagnosis was confirmed as chronic ITP on November 16, 2017. Pet. Ex. 4 at 148. She began taking Promacta and was seen for various follow ups from November 2017 throughout 2018. Id. at 160-61, 169, 179, 183, 188, 191, 197, 200, 209, 215, 218, 224, 227. At her December 7, 2018 follow up, her platelet count dropped to 39,000. Id. at 237. Dr. Kale increased Petitioner's Promacta dosage from 25 mg to 50 mg per day. Id.

⁸ IVIG is "used in the treatment of primary immunodeficiency disorders and [ITP]." Immune Globulin Intravenous (Human), Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=78975 (last visited Feb. 11, 2025).

⁹ Nplate (romiplostim) is "a thrombopoietin receptor agonist used for treatment of [ITP]." Romiplostim, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/ definition?id=44074 (last visited Feb. 11, 2025).

¹⁰ Promacta (eltrombopag olamine) "stimulates platelet production" and is "used for the treatment of thrombocytopenia in patients with chronic [ITP] who have had an insufficient response to other treatments." Eltrombopag Olamine, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15982 (last visited Feb. 11, 2025).

Petitioner's platelet count increased on December 19, 2018 to 248,000 on 50 mg Promacta per day. Pet. Ex. 4 at 248. Dr. Kale switched her to alternating 25 mg and 50 mg every other day, and her platelet count on January 11, 2019 was stable at 75,000. <u>Id.</u> at 248-49. Petitioner mentioned she had gone to urgent care because she was having difficulty breathing, and she had been prescribed prednisone 60 mg. <u>Id.</u> at 244; Pet. Ex. 7 at 6-8. However, Petitioner claimed she had stopped taking the Prednisone prescribed during this appointment three weeks ago. Pet. Ex. 4 at 244. In February 2019, Petitioner's platelet count remained stable on the alternating doses of Promacta. Id. at 257.

Dr. Kale ordered another CT, which was conducted on April 5, 2019, to check on Petitioner's meningioma. Pet. Ex. 4 at 264. The CT showed no change since 2017. <u>Id.</u> at 264, 267. Petitioner began to taper her Promacta by taking 50 mg three days a week and 25 mg the other four days. <u>Id.</u> at 267. In June 2019, this was reduced to 50 mg twice a week and 25 mg five days a week. <u>Id.</u> at 277. Petitioner tolerated this well in August. <u>Id.</u> at 285; Pet. Ex. 11 at 9, 16. On October 9, 2019, Petitioner's platelets remained stable at 153,000, and Petitioner was directed to taper her Promacta to 25 mg every day. Pet. Ex. 11 at 25, 31.

On December 6, 2019, Petitioner was clinically stable and her platelets were stable at 111,000. Pet. Ex. 11 at 39. Her diagnosis remained chronic ITP. <u>Id.</u> at 36. She reported "doing well overall." <u>Id.</u> Review of systems noted that Petitioner had "good energy levels." <u>Id.</u> Fatigue was not reported. <u>See id.</u> at 36-37. ECOG Performance Status was "0." <u>Id.</u> at 38.

Dr. Ni Gorsuch, a hematologist, began seeing Petitioner on March 6, 2020, per Petitioner's request. Pet. Ex. 14 at 19-37. Dr. Gorsuch and Petitioner discussed tapering off Promacta; however, Petitioner decided to stay on Promacta for the time being. <u>Id.</u> at 27. On June 4, 2020, Petitioner began the Promacta taper. Pet. Ex. 21 at 5. Petitioner discontinued Promacta on June 19, 2020. <u>Id.</u> at 15. On July 16, 2020, Petitioner's platelet count was 120,000 and Dr. Gorsuch noted Petitioner was stable without ITP relapse. <u>Id.</u> at 17-19. Petitioner saw her gynecologist for an annual examination on August 7, 2020 and reported regular monthly menses that were not heavy or painful and that she was "doing well" off Promacta. Pet. Ex. 39 at 15-16.

On October 19, 2020, Petitioner was seen by Dr. Gorsuch for a follow up. Pet. Ex. 14 at 23-31. Her ITP had not relapsed. <u>Id.</u> at 24. This remained true throughout 2021. Pet. Ex. 21 at 32-37; Pet. Ex. 24 at 5-9.

Petitioner returned to gynecologist, Dr. Megan Mansell Morris on November 19, 2021 for an annual gynecological examination. Pet. Ex. 39 at 11-12. Petitioner reported regular monthly menses that were not heavy or painful. <u>Id.</u> at 12.

On January 11, 2022, Petitioner reported bruising and bleeding gums and requested blood work. Pet. Ex. 24 at 10. Petitioner "[was] considered to be in remission with a baseline platelet level around 110-120." <u>Id.</u> Her last platelet count in August 2021 was 112,000. <u>Id.</u> If her platelet level went below 100,000, she was directed to see her hematologist. <u>Id.</u> at 11. However, her platelet count at this appointment was 110,000. <u>Id.</u> at 11. Her platelets were tested next on April 12, 2022 and were 106,000. Pet. Ex. 36 at 10.

Petitioner returned to Dr. Gorsuch on September 12, 2022. Pet. Ex. 37 at 5. Dr. Gorsuch documented that Petitioner discontinued Promacta over one year prior and "ha[d] no signs of relapse requiring treatment." Id. He noted her condition was chronic "but not symptomatic." Id. Petitioner denied heavy monthly menstruation and spontaneous bleeding but reported occasional bruises. Id. Petitioner's platelets were 100,00. Id. at 9. Petitioner had "mild anemia" (hemoglobin 11.9) "likely due to recent menstruation," which was to be monitored. Id. at 6, 9. She was instructed to monitor and report any "excessive bruising or spontaneous bleeding." Id. at 10.

On November 1, 2022, Petitioner returned to see her gynecologist, Dr. Morris, for follow up. Pet. Ex. 39 at 3. Her problem list included ITP. Id. She also reported heavy bleeding with menstruation. Id. at 4-5. Petitioner presented "for consultation to help stop periods [due to] ITP. [Petitioner] state[d] menses are regular but are becoming increasingly heavy over time." <u>Id.</u> at 5. Petitioner experienced large clots with her last period and presented to the emergency room. Id. She also reported a platelet drop of 30,000 to 40,000. Id. Dr. Morris recommended an ultrasound to determine best treatment plan, which could include tranexamic acid ("TXA"), Mirena, ablation, and hysterectomy. Id. Petitioner requested a prescription for TXA until she determined a plan. Id. Assessment was "[a]bnormal uterine bleeding," and Petitioner's fingerstick hemoglobin was low at 10.4. Id.

On November 30, 2022, Petitioner underwent an ultrasound which showed findings of "[s]lightly thickened inhomogeneous myometrium" consistent with adenomyosis. 11 Pet. Ex. 39 at 6, 8. Petitioner had not taken TXA yet because her last period in November 2022 "was not very bad and she did not need to take it." Id. at 8. Dr. Morris recommended an intrauterine device ("IUD"), endometrial ablation, or hysterectomy. Id. Dr. Morris opined that given Petitioner's age and suspected adenomyosis, "ablation would be a temporary fix and [] she would likely require[] hysterectomy later." Id. Assessment was "[m]enorrhagia," or "[e]xcessive bleeding in the premenopausal period." <u>Id.</u> at 8.

Petitioner had a telehealth visit with Dr. Gorsuch on December 12, 2022. Pet. Ex. 41 at 6. Her platelet count was 72,000 at this visit. Id. at 8. Dr. Gorsuch's assessment was "minimum change in her platelet count despite having menstruation a day ago. Overall, she does not need treatment for chronic thrombocytopenia." Id. at 6. Dr. Gorsuch also noted Petitioner had mild anemia (hemoglobin 11.2) likely due to her blood loss for her menstrual cycle and continued to heavy bleeding during menstruation at times. Id. at 6, 8. Petitioner denied excessive fatigue, shortness of breath or dizziness. Id. at 6. Dr. Gorsuch added that Petitioner's anemia was "not symptomatic." Id.

¹¹ Adenomyosis is "a benign condition characterized by endometrial glands and stroma within the myometrium, accompanied by hypertrophy of the myometrium." Adenomyosis, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=965 (last visited Feb. 11, 2025).

Petitioner returned for an annual examination with Dr. Morris on January 16, 2023. Pet. Ex. 42 at 5. Petitioner reported no gynecological complaints and regular menses that were not heavy or painful. Id. at 7. Her menses lasted five days, and two of those days she had a heavy flow. Id. She also noted she "[h]a[d] not needed to take TXA." Id. Petitioner's platelets were tested on April 19, 2023 and were 116,000. Pet. Ex. 40 at 6, 12. Fingerstick hemoglobin was normal at 12.8. Pet. Ex. 42 at 8, 25.

Her next visit to a health care provider was April 19, 2023, when she saw Physician Assistant ("PA") Anna Becker for an annual health review. Pet. Ex. 40 at 4. At that visit, Petitioner reported having "situational anxiety, mostly triggered by specific situations" including "going to the doctor's offices, checkout lines in grocery stores, [and] driving on the highway." Id. She had developed "anxiety attacks" which led to hyperventilation and dizziness. Id. These occurred "a few times a week," resolving when she would leave the situation. Id. She reported seeing a counselor, which she "found helpful." 12 Id. She also tried using "deep breaths." Id. Assessments included "[a]nxiety." Id. at 5. Treatment was initiated with Alprazolam 0.25 mg, twice daily as needed for acute anxiety. Id. at 6. A prescription for Xanax was also given to be taken as needed. Id. Her platelet count at this visit was 116,000. Id.

Ms. Becker held a video visit with Petitioner on May 24, 2023 for follow up of her anxiety. Pet. Ex. 51 at 4. Petitioner reported that she had taken Xanax two to three times since the prior visit, and while the medication improved her anxiety, it did not completely resolve it. Id. Driving had been more difficult. Id. Petitioner also described being very anxious when she cannot leave a situation. Id. She was especially concerned about upcoming jury duty. Id. Assessment was anxiety. Id. at 5. Treatment with Alprazolam as needed was continued. Id. at 5.

On September 12, 2023, Petitioner saw Dr. Gorsuch. Pet. Ex. 49 at 5. Petitioner's platelets were 147,000. Id. at 8. Assessment noted Petitioner continued to have minimal changes in her platelets "despite having no treatment for a long time." Id. at 5. Dr. Gorsuch noted Petitioner "[did] not need treatment for chronic thrombocytopenia" and Petitioner agreed to continue following up with only primary care. Id. She was also instructed to monitor for signs and symptoms of recurrent ITP. Id. At this visit, Dr. Gorsuch also noted that Petitioner had intermittent menorrhagia, "[o]therwise, [she had] no signs of other bleeding." Id. at 6. She had an appointment scheduled to see her gynecologist to discuss treatment of her menorrhagia. Id. at 5. Hemoglobin was low at 11.9. Id. at 8. Final diagnoses were ITP and "[e]xcessive and frequent menstruation." Id. at 24.

In January 2024, Petitioner saw Ms. Becker and requested her platelets be checked due to spotting when not on her period, which she reported was unusual for her. Pet. Ex. 51 at 7. Petitioner "denie[d] recent easy bruising[] [and] easy bleeding." Id. Petitioner's platelet count was 149,000, which was "stable and in the higher range for [Petitioner]." Id. at 9-10. Petitioner

¹² On February 7, 2025, Petitioner filed a status report, stating "she never saw a mental health counselor for her anxiety related to her ITP." Pet. Status Rept., filed Feb. 7, 2025, at 1 (ECF No. 132). Petitioner believed this notation was an error. Id.

also reported that her anxiety had slightly worsened and she had experienced several episodes at the grocery store, associated with palpitations, increased heart rate, shortness of breath, and anxiety. Id. at 7. The episodes were short and resolved after five to 10 minutes. Id. Petitioner noted that she had a high level of stress in her life at the time. Id. Assessment included history of ITP and anxiety. Id. at 8.

Petitioner also saw her gynecologist for an annual examination in January 2024. Pet. Ex. 53 at 8. Petitioner reported her "recent episode of intermenstrual spotting" as well as two "very heavy days of clotting" before her period was over. <u>Id.</u> at 10. Petitioner reported she "[h]a[d] not needed to take TXA." Id. Petitioner expressed interest in a hysterectomy. Id. at 12.

Repeat blood work one month later, on February 16, 2024, revealed a platelet count of 82,000. Pet. Ex. 51 at 13.

Petitioner returned to Dr. Morris on July 1, 2024 for a consult regarding a hysterectomy. Pet. Ex. 53 at 3, 5. At this visit, Petitioner reported "worsening periods since 10/2022.... [Petitioner] strongly desire[d] to avoid hormonal [treatment]. She state[d] her last period in June was the heaviest she has had to date and she passed large clots. . . . Menses do occur regularly but are extremely heavy and painful." Id. at 5. Dr. Morris noted that Petitioner had ITP and her platelets were last tested in May 2024 and were 100,000.¹³ Id. Petitioner had previously been prescribed TXA, although she never took it when last prescribed. Id. at 6. Petitioner requested a hysterectomy. Id. Labs drawn that day showed normal hemoglobin of 12.4 and platelets of 96,000 (range 150,000 to 450,000). ¹⁴ Id. at 23. Dr. Morris recommended a robotic hysterectomy due to Petitioner's obesity and ITP and referred Petitioner to a surgeon. <u>Id.</u> at 6.

On July 29, 2024, Petitioner saw Dr. Amr Sherif Mohamed Rifaa El Haraki in consultation. Pet. Ex. 54 at 311. Petitioner reported "intense vaginal bleeding with her periods since 2016." Id. Due to her ITP diagnosis, Petitioner was "worried about heavy bleeding due to her heavy periods." <u>Id.</u> An endometrial biopsy and ultrasound were performed. <u>Id.</u> at 313. The ultrasound showed "[b]lurring of the endometrial myometrial junction with possible myometrial cystic spaces, which can be seen in the setting of adenomyosis." Id. It also showed "[r]estricted movement between the uterine and bowel surfaces" and "[p]ossible cystic structures along the posterior uterine serosa and in the left adnexa" that were not well visualized. Id. The endometrial biopsy showed "[p]roliferative endometrium" and "[b]enign squamous epithelial cells," but did not show any other abnormalities. Id. at 316. Assessment was abnormal uterine bleeding ("AUB") and history of ITP. Id. at 314. Petitioner was offered medical treatment but she preferred surgical intervention. Id. The plan was for a vaginal hysterectomy with bilateral salpingectomy. Id.

¹³ Lab records confirming this blood work were not filed.

¹⁴ This record documented "[a]ctual platelet count may be somewhat higher than reported due to aggregation of platelets in this sample." Pet. Ex. 53 at 23.

Petitioner underwent a total laparoscopic hysterectomy on August 23, 2024 as an outpatient procedure. Pet. Ex. 54 at 28. Pre-operative diagnoses were AUB and ITP. <u>Id.</u> Operative findings included Stage IV endometriosis. ¹⁵ <u>Id.</u> at 28-29. There were no complications and she was discharged the same day. Id. at 27-30.

No additional medical records have been filed.

B. Petitioner's Affidavit and Declarations

1. Pre-Ruling on Entitlement Affidavit and Declaration¹⁶

Prior to the vaccination at issue, Petitioner "was healthy, active[,] and had no autoimmune diseases or hematological disorders, or any history of autoimmune disease or hematological disorders." Pet. Ex. 32 at ¶ 3. Petitioner received her flu vaccine on October 9, 2016. Pet. Ex. 2 at ¶ 4. She started to notice bruising on the front and back of her thighs in mid-November 2016, around two weeks prior to her birthday on November 27, 2016. Id. at ¶¶ 10, 12. These bruises did not fade as ordinary bruises she had in the past did. Id. at ¶ 10.

On November 30, 2016, Petitioner had her menstrual period. Pet. Ex. 2 at ¶ 15. Petitioner's cycle lasted for 10 days instead of her normal four to five days and she felt dizzy, lightheaded, fatigued, and weak. <u>Id.</u> She continued to experience "spontaneous bruising, dizziness, lightheadedness, fatigue, weakness, and heavy menstruation[]." <u>Id.</u> at ¶ 16. On December 7, 2016, Petitioner visited her OB/GYN where she underwent a full panel of blood work. <u>Id.</u> at ¶ 18. On December 8, 2016, Petitioner's physician notified her that her "platelets were critically low at 12,000 and that [she] needed to see a hematologist as soon as possible." <u>Id.</u> at ¶ 19.

Dr. Kale saw Petitioner on December 12, 2016. Pet. Ex. 2 at \P 21. At this appointment, she was diagnosed with ITP and was prescribed 60 mg of prednisone. <u>Id.</u> Petitioner's platelet count increased to 126,000 the following week and she began a prednisone taper. <u>Id.</u> at \P 22.

Petitioner returned for a follow up visit on December 27, 2016. Pet. Ex. 2 at ¶ 23. Her platelet count had dropped to 32,000. <u>Id.</u> She restarted prednisone and her platelet count increased. <u>Id.</u> Dr. Kale advised her she had ITP that was responsive to steroids and steroid dependent. <u>Id.</u> In January 2017, Petitioner switched to Rituxan therapy and began to taper her prednisone. <u>Id.</u> at ¶ 24. Petitioner's platelets increased by early February 2017. <u>Id.</u>

¹⁵ Endometriosis is "a condition in which tissue containing typical endometrial granular and stromal elements occurs in locations outside the uterine cavity, chiefly on the ovaries and pelvic peritoneum." <u>Endometriosis</u>, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=16340 (last visited Feb. 11, 2025).

¹⁶ Petitioner submitted an affidavit executed on September 24, 2019 and a declaration executed on March 3, 2022. Pet. Exs. 2, 32.

Following a nosebleed, Petitioner returned to Dr. Kale's office on February 12, 2017. Pet. Ex. 2 at ¶ 25. Her platelet count had dropped to 9,000. <u>Id.</u> She immediately reported to the hospital for possible IVIG treatment. <u>Id.</u> She was admitted to the hospital on February 14, 2017, where she received two doses of IVIG and Nplate treatments. <u>Id.</u> at ¶ 26. She was discharged the following day. <u>Id.</u> By March 2017, her platelets increased to 191,000 and she remained on 20 mg of prednisone. <u>Id.</u> Between March 2017 and October 2017, Petitioner was consistently on prednisone and receiving weekly Nplate shots. <u>Id.</u> at ¶ 27. Her platelets fluctuated greatly over this period. <u>Id.</u>

Petitioner saw Dr. Ma at UNC Healthcare on October 17, 2017 for a second opinion. Pet. Ex. 2 at ¶ 28. Dr. Ma suggested Cellcept, Promacta, or a splenectomy as alternative courses of treatment. Id. She recommended repeating Rituxan if the splenectomy failed. Id. However, since Petitioner was on Nplate successfully, Dr. Ma recommended staying on Nplate or switching to Promacta. Id.

From October 2017 to November 2017, Petitioner continued to take prednisone and receive weekly Nplate shots. Pet. Ex. 2 at \P 29. On November 16, 2017, Petitioner began taking Promacta at 25 mg per day. <u>Id.</u> She remained on Promacta, taking 25 mg every day except Mondays and Fridays, when she took 50 mg. <u>Id.</u> at \P 30.

Petitioner weaned off Promacta in June 2020. Pet. Ex. 32 at ¶ 14. She followed up with her hematologist annually and had her platelets checked twice a year with her hematologist and at her yearly physical. <u>Id.</u> Her platelets remain lower than normal; however, they are stable enough for her to feel comfortable. <u>Id.</u>

Petitioner explained how her diagnosis has affected her emotionally, physically, and psychologically. Pet. Ex. 2 at ¶ 31. She described that

[p]hysical activity is harder now. The long list of medications and treatments [she has] been on have been very hard on [her] body. The steroids (prednisone and dexamethasone) have made [her] shoulders, hips, and knees ache. They have also caused significant weight gain and [she is] very sensitive to heat now and overheat[s] easily. This limits [her] from being able to go outside or do things with [her] daughter a lot during the hot summer months. [Her] moods are affected, and [she has] a lot of mood swings. [She] also ha[s] extreme fatigue. [She] ha[s] talked to [her] doctor about this, especially insomnia.

Id.

When Petitioner's counts are lower, she must be extremely careful. Pet. Ex. 2 at ¶ 32. She explained that her social life has been affected by her diagnosis. <u>Id.</u> at ¶ 33. She constantly worries during her menstrual cycle every month. <u>Id.</u> She looks for bruises and blood blisters and worries she will catch something during cold/flu season that would cause her platelets to decrease. <u>Id.</u> Petitioner also claims her diagnosis has also impacted her ability to work. <u>Id.</u> at ¶ 34. She cannot work more than part time due to her extreme fatigue that results from her medications. Id. Petitioner also suffered financially due to her diagnosis. Id. at ¶ 35.

2. Supplemental Declaration ¹⁷

Petitioner's supplemental declaration, executed October 2, 2023, includes information covered in her previous affidavits and provides additional information about her clinical course, consistent with her affidavits and medical records. See Pet. Ex. 50. Specifically, as it relates to anxiety, Petitioner described the mental toll of ITP; she constantly checks for bruises, worries about her menstrual cycle every month, and worries during flu seasons that she could catch an illness that could decrease her platelet counts. Id. at 4-6. She stated, "[t]he anxiety is very real." Id. at 6.

3. Affidavit and Declarations Regarding Lost Wages

Specific to her claim for past and future last wages, in her first affidavit, executed September 24, 2019, Petitioner averred that she worked part-time at a preschool. Pet. Ex. 2 at ¶ 34. She did not believe she would work more than part time due to the extreme fatigue she experienced from her ITP and medications. <u>Id.</u>

On March 3, 2022, Petitioner signed a declaration describing her condition at that time, but she did not discuss her employment. See Pet. Ex. 32 at 1-5. She was not taking any medications for her ITP at that time, but she stated that she continued to experience fatigue, joint pain, and weight issues. Id. at ¶ 14.

In her last declaration, executed October 2, 2023, Petitioner explained that her husband was the primary earner in her family, and that for the past 10 years, she held part-time employment so that she could be home with her daughter. Pet. Ex. 50 at ¶ 22. She explained that during the COVID pandemic, there was a period of time that she did not work because she was too anxious about becoming sick due to her ITP. <u>Id.</u> at ¶ 21. Additionally, she explained that she currently works part time and has not applied for full-time positions because she does not believe that she could handle full-time employment. <u>Id.</u>

Petitioner's daughter was born in 2010, and Petitioner stayed home with her for five years. Pet. Ex. 50 at ¶ 22. In 2015, Petitioner's daughter started preschool, and Petitioner began substitute work at the same school. <u>Id.</u> In 2016, when her daughter started kindergarten, Petitioner began working a permanent part-time position, five days per week, from 9:00 a.m. until 1:00 p.m. <u>Id.</u> She continued to work after she developed ITP, although "it became increasingly more difficult." <u>Id.</u> However, after the COVID pandemic began, Petitioner asserted that "[i]t was nearly impossible for [her] to work at the preschool due to [her] ITP, frequent illnesses[,] and severe anxiety [she] had about COVID" and her illness. <u>Id.</u> She returned to work in October 2022, at early morning drop-off for 1.5 hours per day, five days per week. <u>Id.</u> at ¶ 23.

¹⁷ Although labeled an affidavit, it is not notarized, and is therefore referred to as a declaration.

Petitioner stated that when she began working at the preschool in 2016, her plan was to work at the school until her daughter started middle school and "then find employment working formal full-time hours." Pet. Ex. 50 at ¶ 23. However, she stated that due to her illness, "it is exceedingly difficult" to work full time due to fatigue and the risk of illness. <u>Id.</u> Currently, Petitioner works a school year calendar, late August through late May. <u>Id.</u> at ¶ 24. Before her ITP, Petitioner had planned to work full-time in a preschool during the school years, and to work at camps or programs in the summer to earn money during summer months. <u>Id.</u>

III. EXPERT REPORTS

A. Petitioner's Expert, Dr. Abhimanyu Ghose

Dr. Ghose is board certified in hematology oncology and internal medicine. Pet. Ex. 43 at 1. He is an expert in hematological disorders, including ITP. <u>Id.</u>

He explained that patients with ITP can be asymptomatic. Pet. Ex. 43 at 2. However, "many [] suffer from the consequences of low platelets, which are typically bleeding manifestations" that "can vary from bruising on the skin, bleeding from the nose, heavy periods," and hemorrhage. <u>Id.</u> ITP can also lead to fatigue and "worsened quality of life." <u>Id.</u> Dr. Ghose cited McMillan et al., ¹⁸ which reported on the quality of life in adults with chronic ITP and "concluded that patients with chronic ITP had a lower quality of life than people without ITP and there was a reasonable likelihood that someone with chronic ITP would have negative impacts on their work or school such as absences, missing promotions or failing to advance." <u>Id.</u> at 2-3 (citing Pet. Ex. 17(a)).

Dr. Ghose opined Petitioner was in good health prior to developing ITP. Pet. Ex. 43 at 3. "[Her] disease was refractory to steroids and challenging to treat warranting frequent lab work through blood draws, doctor visits[,] and even traveling for second opinion." <u>Id.</u> "She continues to have fluctuations in her platelet counts even though she is not dependent on medication or Promacta for her chronic ITP. Her platelets continue to be below normal, indicating that she has an ongoing chronic ITP that is not overly symptomatic," although she has "ongoing spontaneous bruising and heavy menstrual cycles." <u>Id.</u> Petitioner is also "prone to ongoing bouts of increased fatigue, immune system complications, and frequent sickness." <u>Id.</u> Although she is no longer on medication, Petitioner requires ongoing monitoring. <u>Id.</u> Dr. Ghose opined "there is a reasonable likelihood of relapse in her condition since it is chronic." <u>Id.</u> He added, "[Petitioner's] discontinuance of Promacta is not a sign that her chronic ITP is in remission or cured. Quite the opposite, she is at a 15-53% risk of relapse given her diagnosis." <u>Id.</u> at 4.

With regard to her chronic autoimmune illness and the nature of Petitioner's work in childcare at a preschool, Dr. Ghose opined that he "would reasonably expect her to be prone to ongoing infections and illnesses that are abundant in that setting." Pet. Ex. 43 at 4. Although "she is able to become employed," Petitioner "is at risk for frequent illnesses, absences, and

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¹⁸ Robert McMillan et al., <u>Self-Reported Health-Related Quality of Life in Adults with Chronic Immune Thrombocytopenic Purpura</u>, 83 Am. J. Hematology 150 (2008).

inability to earn promotions due to her erratic attendance and participation in the workforce." <u>Id.</u> "She may also have issues maintaining employment with frequent illnesses, increased fatigue, body aches, and immune complications which will prevent her from advancing in her career and increasing her annual earnings." Id.

Dr. Ghose concluded Petitioner "should be able to continue working in her field at the current part-time allotment but with limitations." Pet. Ex. 43 at 4. "[He] expect[s] that [Petitioner] will be unable to maintain full-time employment or common part-time hours (20-25 hours per week) due to her chronic ITP and the symptoms associated with it." Id.

B. Respondent's Expert, Dr. Lisa Baumann Kreuziger

Dr. Kreuziger agreed that Petitioner, due to her use of Promacta, she "can have long-term remission after discontinuation of therapy, but monitoring is needed as relapse is possible." Resp. Ex. CC at 2.

She also agreed ITP patients "can experience fatigue and fatigue can affect their quality of life." Resp. Ex. CC at 2. But she contended that "[f]atigue [was] not consistently documented" in Petitioner's records. <u>Id.</u> at 3. "Therefore, there is not corroborating evidence within the medical record of severe fatigue that would affect her ability to work." <u>Id.</u>

In response to Dr. Ghose's assertion that Petitioner will have frequent illnesses due to her work in childcare, Dr. Kreuziger opined Petitioner had experienced illnesses prior to her ITP, "and if frequent illnesses occurred, they would not be attributable to her ITP." Resp. Ex. CC at 3.

Dr. Kreuziger also addressed Petitioner's complaint of heavy menstrual bleeding. Resp. Ex. CC at 4. "When platelet counts are low, heavy menstrual bleeding can occur," explained Dr. Kreuziger. <u>Id.</u> Thus, "[c]ontrolling her menstrual cycles would not influence her platelet counts."

Overall, she opined Petitioner requires monitoring with appointments and bloodwork. Resp. Ex. CC at 4. She is not symptomatic, and she does not require subspecialty (hematology) care. <u>Id.</u> Despite Dr. Ghose's assertions, Petitioner's treating physicians and Petitioner's medical records do not consistently document fatigue or other symptoms "that would impact her ability to work or to work at the level she alleges." <u>Id.</u> Thus, Dr. Kreuziger opined "[Petitioner's] ITP does not require treatment outside of the need for monitoring through her primary care physician." Id.

C. Staci L. Schonbrun, Labor Market Consultant

Ms. Schonbrun summarized Petitioner's employment history. Pet. Ex. 47 at 5. Petitioner was a preschool teacher at the time of her vaccination and subsequent development of ITP. <u>Id.</u> Petitioner was out of work for periods of time in 2016, but largely maintained her employment until the COVID pandemic began in March 2020. <u>Id.</u> Petitioner did not return to work following the preschool's reopening. <u>Id.</u> Petitioner reported that in 2016 "she continued

working but with difficulties," including fatigue and sickness, which "made it difficult to maintain her ITP and blood counts." <u>Id.</u> "When the COVID shutdown occurred and she was no longer working, she found that her blood counts stabilized and by June 2020 she came off her medication." <u>Id.</u> Petitioner "was afraid to return to work because she was fearful of coming out of remission and going back on the medication which was problematic." <u>Id.</u> She returned to work in October 2022, working 1.5 hours per day as opposed to four hours per day. <u>Id.</u> Based on information obtained, Ms. Schonbrun believed the most significant issue is Petitioner's fatigue, followed by joint pain and anxiety. <u>Id.</u>

With regard to earning capacity, Ms. Schonbrun conceded "[f]rom 2017 to 2019[,] [Petitioner] did return to work in a similar capacity and when averaged this results in annual earnings of \$6,632.97," which is "a reasonable measure of [Petitioner's] pre-injury earning capacity during the years that her daughter is in school as she is the primary caregiver." Pet. Ex. 47 at 8. Once Petitioner's daughter graduated from high school "it is reasonable that [Petitioner] pre-injury would have worked in the same or similar capacity, but on a full-time rather than part-time basis." <u>Id.</u> Ms. Schonbrun noted that in 2022, "82.2% of employed mothers whose youngest children were between 6-17 worked in full time." <u>Id.</u>

Petitioner has worked 1.5 hours per day for five days per week since returning to work in October 2022. Pet. Ex. 47 at 9. Ms. Schonbrun opined that "[i]t is probable that her present wages are representative of her post-injury earning capacity." Id. Ms. Schonbrun calculated Petitioner's past and future lost wages using the median wage of childcare workers in North Carolina and Petitioner's earning capacity pre- and post-injury. Id. Because "Dr. Ghose opined that [Petitioner] would exit the labor force earlier than an average person due to her medical condition," and due to her current hours, Ms. Schonbrun "did not further reduce her participation rate but [] utilized her present employment as a permanent basis over the remainder of her work life expectancy instead." Id. at 10.

IV. PARTIES' CONTENTIONS

A. Pain and Suffering

1. Petitioner's Contentions

In her first submission, Petitioner requested a pain and suffering award of \$200,000, but then increased her request to \$250,000.00 in her reply brief. Pet. Brief at 1; Pet. Reply Br. at 1-2, 1 n.1. Petitioner contends her case has been severe, lasting over seven years with continued treatment and procedures due to the residual effects of her ITP. Pet. Reply Br. at 2.

2. Respondent's Contentions

Respondent argues that based on the facts of this case, Petitioner should be awarded \$70,000.00 for pain and suffering. Resp. Br. at 6. Respondent contends Petitioner was actively treated for her ITP for three-and-one-half years, from December 2016 until June 2020. <u>Id.</u> at 6. In the first 11 months, Petitioner's platelet counts waxed and waned. <u>Id.</u> She was given a diagnosis of chronic ITP in November 2017 and prescribed Promacta. <u>Id.</u> Thereafter, her

platelets stabilized. <u>Id.</u> Petitioner began to wean off Promacta and by June 2020, she had discontinued taking Promacta. <u>Id.</u> Respondent asserts that while she was on Promacta, Petitioner did not have any relapse in symptoms, and that she has not had any relapses since stopping Promacta in June 2020. <u>Id.</u> at 6-7. Additionally, Respondent notes Petitioner's expert hematologist, Dr. Ghose, agreed Petitioner has not had a relapse of her ITP since stopping Promacta. <u>Id.</u> at 8 (citing Pet. Ex. 43 at 2-3).

As to duration, Respondent contends Petitioner's injury lasted three-and-one-half years, until June 2020 and that there is no evidence in the medical records to support Petitioner's contention of ongoing ITP symptoms. Resp. Br. at 8.

B. Lost Wages

1. Petitioner's Contentions

Petitioner seeks an award of total lost earnings in the amount of \$281,268.00, from 2016 to 2047. Pet. Br. at 26; Pet. Reply Br. at 1. This amount includes lost earnings of \$14,994.00 from 2016 to 2023 and Petitioner's lost earnings capacity of \$266,275.00 from 2023 to 2047. Pet. Br. at 26.

2. Respondent's Contentions

Respondent contends "[P]etitioner experienced a loss of earnings from September 2020 through the 2023-2024 school year." Resp. Br. at 11. Respondent's expert, Patrick F. Kennedy, Ph.D., calculated these lost earnings to be \$14,694.00. <u>Id.</u> at 11-12 (citing Resp. Ex. DD at 4, 22). However, Respondent disagrees that Petitioner is entitled to future lost earnings. Id. at 12.

C. Unreimbursable Expenses

The parties agree on an amount of past unreimbursable expenses. Resp. Br. at 4; Pet. Reply Br. at 1. They agree that Petitioner should be awarded \$7,676.42 for past unreimbursed expenses. Resp. Br. at 4; Pet. Br. at 30; Pet. Reply Br. at 1.

V. LEGAL FRAMEWORK AND ANALYSIS

Petitioner bears the burden of proof with respect to each element of compensation requested. <u>Brewer v. Sec'y of Health & Hum. Servs.</u>, No. 93-0092V, 1996 WL 147722, at *22-23 (Fed. Cl. Spec. Mstr. Mar. 18, 1996).

A. Pain and Suffering

Compensation awarded pursuant to the Vaccine Act shall include "[f]or actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed \$250,000." § 15(a)(4).

There is no formula for assigning a monetary value to a person's pain and suffering and emotional distress. I.D. v. Sec'y of Health & Hum. Servs., No. 04-1593V, 2013 WL 2448125, at *9 (Fed. Cl. Spec. Mstr. May 14, 2013) ("Awards for emotional distress are inherently subjective and cannot be determined by using a mathematical formula."); Stansfield v. Sec'y of Health & Hum. Servs., No. 93-0172V, 1996 WL 300594, at *3 (Fed. Cl. Spec. Mstr. May 22, 1996) ("[T]he assessment of pain and suffering is inherently a subjective evaluation."). Factors to be considered when determining an award for pain and suffering include: (i) awareness of the injury; (ii) severity of the injury; and (iii) duration of the suffering. I.D., 2013 WL 2448125, at *9 (quoting McAllister v. Sec'y of Health & Hum. Servs., No. 91-1037V, 1993 WL 777030, at *3 (Fed. Cl. Spec. Mstr. Mar. 26, 1993), vacated & remanded on other grounds, 70 F.3d 1240 (Fed. Cir. 1995)).

The undersigned may look to prior pain and suffering awards to aid in the resolution of the appropriate amount of compensation for pain and suffering in this case. See, e.g., Doe 34 v. Sec'y of Health & Hum. Servs., 87 Fed. Cl. 758, 768 (2009) (finding that "there is nothing improper in the chief special master's decision to refer to damages for pain and suffering awarded in other cases as an aid in determining the proper amount of damages in this case"). The undersigned may also rely on her experience adjudicating similar claims. Hodges v. Sec'y of Health & Hum. Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (noting that Congress contemplated the special masters would use their accumulated expertise in the field of vaccine injuries to judge the merits of individual claims). Importantly, however, it must also be stressed that pain and suffering is not determined based on a continuum. See Graves v. Sec'y of Health & Hum. Servs., 109 Fed. Cl. 579 (2013).

In <u>Graves</u>, Judge Merow rejected the special master's approach of awarding compensation for pain and suffering based on a spectrum from \$0.00 to the statutory \$250,000.00 cap. Judge Merow noted that this constituted "the forcing of all suffering awards into a global comparative scale in which the individual petitioner's suffering is compared to the most extreme cases and reduced accordingly." <u>Graves</u>, 109 Fed. Cl. at 589-90. Instead, Judge Merow assessed pain and suffering by looking to the record evidence, prior pain and suffering awards within the Vaccine Program, and a survey of similar injury claims outside of the Vaccine Program. Id. at 595.

Application of the three factors in this matter begins with awareness. Here, there is no dispute regarding this element pain and suffering. Petitioner was fully aware of her ITP and its relevant sequalae.

Regarding severity, the undersigned largely agrees with the arguments set forth in Petitioner's briefs, outlining the evidence establishing that Petitioner's ITP was severe. See Pet. Br. at 18-23; Pet. Reply Br. at 3-9. Based on the undersigned's review of the records, affidavit, and declarations, the evidence supports a finding that Petitioner's ITP caused bruising, nosebleeds, heavy bleeding during menses, dizziness from anemia, low platelet counts, mild anemia, frequent visits to physicians, frequent diagnostic and laboratory testing, monitoring, and treatment. She experienced anxiety over going to medical appointments and due to her worry of relapse.

Before she went into remission, her platelet counts would acutely decrease and then improve with therapy. Over the course of two years, from December 2016 to December 2018, Petitioner's platelet counts were 50,000 or below on at least seven occasions.

Date	Platelet Count
December 8, 2016	12,000
December 27, 2016	32,000
January 3, 2017	42,000
January 30, 2017	11,000
February 13, 2017	9,000
August 10, 2017	50,000
December 7, 2018	39,000

Treatment included significant doses of prednisone, as well as multiple different medications, including Rituxan, dexamethasone, IVIG, Nplate, and Promacta. Steroids made her feel edgy and gain weight. Petitioner sought treatment many times when her platelets were low, including visits to Urgent Care and one admission to the hospital.

Petitioner was diagnosed with severe labile immune thrombocytopenia due to the refractory nature of her illness and lack of remission in spite of treatment with several different medications given during the early years of therapy, and before treatment with Promacta. In 2017, Petitioner was diagnosed with chronic ITP. She began Promacta in November 2017 and continued to take it until June 2020, until she was diagnosed as stable with no relapses. In 2022, Dr. Gorsuch, her hematologist, noted her condition remained chronic, although he determined she was asymptomatic.

In 2017, Petitioner reported a "sense of anxiety" and feeling "a little edgy" on steroids. Pet. Ex. 4 at 38, 42. She was prescribed lorazepam, but did not fill the prescription. In 2023, Petitioner sought treatment for situational anxiety and anxiety attacks triggered by events that included going to doctors' offices. While visits to doctors' offices were not the only situations that created anxiety, the evidence shows that they were stress inducing. Treatment included medication as needed. Further, Petitioner's affidavit and declarations describe the worry she experienced over her concerns about relapsing. She explained how she worries monthly during her menstrual cycle and during cold/flu season. She also constantly checks for bruises and blood blisters.

Petitioner also suffered from heavy menses from 2016 until 2024, when she elected to undergo a hysterectomy. Her records establish there were two diagnoses, AUB and ITP, relevant to her decision to undergo a hysterectomy. During her early clinical course of ITP, prior to her remission, her excessive bleeding during menstruation was attributed in part to her low platelet counts. Her platelets were first tested in December 2016 by her OB/GYN following Petitioner's complaints of a prolonged, heavy period. Her platelets were 12,000, which prompted her to see a hematologist, leading to her ITP diagnosis. In part, she was diagnosed with ITP after she reported heavy periods.

However, after Petitioner began taking Promacta, and her platelet counts improved, it is not clear what role her ITP played in her heavy bleeding during menses. At Petitioner's annual examination with her gynecologist in August 2020, following her discontinuation of Promacta, Petitioner reported her menses were not heavy or painful. At her next annual examination in November 2021, Petitioner reported regular monthly menses that were not heavy or painful. Petitioner denied heavy monthly menstruation at a visit with Dr. Gorsuch in September 2022. But, in November 2022, Petitioner reported heavy bleeding with menstruation to her gynecologist, Dr. Morris, who suspected adenomyosis. By her visit with Dr. Morris in January 2023, Petitioner reported no gynecological complaints and regular menses that were not heavy or painful. One year later, in January 2024, Petitioner reported to her gynecologist that she had intermenstrual spotting and two days of clotting during her period, and she expressed interest in a hysterectomy. Petitioner returned to Dr. Morris on July 1, 2024 for a consult regarding a hysterectomy, reporting worsening periods since October 2022. The pathology report from her endometrial biopsy in July 2024 showed "[p]roliferative endometrium." Pet. Ex. 54 at 316. The surgeon who performed her hysterectomy in August 2024 reported that operative findings included Stage IV endometriosis.

Neither Dr. Morris nor the surgeon opined that Petitioner's ITP caused or contributed to her AUB in 2024, or was otherwise an indication for hysterectomy. The records do not show that Petitioner experienced untoward bleeding or any other complications of her hysterectomy due to her ITP. The undersigned notes that Petitioner did suffer heavy bleeding prior to her treatment with Promacta, and that during at least some of that time, her ITP may have played a role in her bleeding as evidenced by her abnormally low platelet counts. Since that time, however, while there have been an occasional references to ITP in the context of Petitioner's heavy menses, these are generally reports by Petitioner of her history of ITP. There is no opinion by Petitioner's treating physicians or the medical experts that her hysterectomy in 2024 was medically indicated due to ITP.

Petitioner cited medical literature for the proposition that ITP has been associated with heavy menstrual bleeding. Pet. Reply Br. at 12-13 (citing Pet. Ex. 20(a); 19 Pet. Ex. 20(aa)). 20 The article from Arnold and Cuker, however, does not support a finding that Petitioner's hysterectomy was indicated due to her ITP at the time that it was performed in 2024. The second article, by Provan et al., discusses criteria for diagnosis and recommendations for treatment of ITP; it does not state that patients with stable ITP who have heavy menstrual bleeding should be treated with hysterectomy. And the third article cited, authored by van Dijk et al., ²¹ concluded

¹⁹ Drew Provan et al., <u>Updated International Consensus Report on the Investigation and</u> Management of Primary Immune Thrombocytopenia, 3 Blood Advances 3780 (2019).

²⁰ Donald M. Arnold & Adam Cuker, Immune Thrombocytopenia (ITP) in Adults: Clinical Manifestations and Diagnosis, UpToDate, https://www.uptodate.com/contents/immunethrombocytopenia-itp-in-adults-clinical-manifestations-and-diagnosis (last updated July 2, 2020).

²¹ Petitioner did not file this article. Wobke E.M. van Dijk et al., Menstrual Problems in Chronic Immune Thrombocytopenia: A Monthly Challenge-A Cohort Study and Review, 198 Brit. J. Haematology 753 (2022).

women may be prone to menstrual problems. However, their conclusion does not support a finding that heavy menstrual bleeding due to ITP necessitates a hysterectomy.

The medical literature cited by Petitioner establishes that women with ITP may experience heavy bleeding, but it does not support a finding that hysterectomy is indicated here, where in 2024, when Petitioner underwent her hysterectomy, her platelet count and ITP were stable, and where there is no medical opinion suggesting that surgery was warranted based on her ITP. Moreover, her physicians documented other causes of her AUB, including adenomyosis and endometriosis.

Further, there is no opinion by either parties' experts that Petitioner's hysterectomy was performed due to heavy bleeding or other sequelae of her ITP.

Finally, the undersigned agrees that Petitioner's platelet counts, while stable and within levels that do not cause active bleeding, are not within normal limits, and this fact increases the value of her pain and suffering award. The most recent platelet counts in the medical records show that in May 2024, Petitioner's platelet count was 100,000 and in July 2024, it was 96,000 (normal values 150,000-450,000). However, while this is an important fact relevant to an assessment of Petitioner's award for pain and suffering, there is no evidence that these platelet levels were the reason for her hysterectomy, as discussed above.

As for duration, the undersigned finds that Petitioner's experienced the most severe phase of her ITP from 2016 to 2018, when her platelet counts were erratic and her illness was refractory to medical treatment. After December 2018, treatment with Promacta was effective, and Petitioner's severely labile course became stable. However, she continued to receive medical treatment until June 2020. From 2018 until 2020, Petitioner's course was less severe, but it continued to require medical treatment. In 2020, Petitioner was able to discontinue her medication and her condition became generally asymptomatic thereafter. The undersigned acknowledges that Petitioner has and continues to experience emotional distress due to worry and stress related to the potential of relapse. The undersigned finds that the duration of Petitioner's severely labile condition was two years and the duration of her moderate condition lasted another two years. Since June 2020, she has been largely asymptomatic. During these past four to five years, however, she has experienced some ongoing distress due to the threat of and worry about relapse.

There are no reasoned decisions to inform the undersigned as to the value of Petitioner's pain and suffering. Petitioner cites to <u>Ebenstein</u> for the proposition that it represents another case of severe ITP which warrants a higher award for pain and suffering. <u>See Ebenstein v. Sec'y of Health & Hum. Servs.</u>, No. 06-0573V, 2010 WL 5113185 (Fed. Cl. Spec. Mstr. Sept. 1, 2010) (finding Petitioner entitled to compensation). However, damages in that case were resolved through a proffer, with all items of damages combined into one total, so that the amount proffered for pain and suffering is not known. <u>See Ebenstein v. Sec'y of Health & Hum. Servs.</u>, No. 06-0573V, 2012 WL 1611850 (Fed. Cl. Spec. Mstr. Apr. 3, 2012).

Relying on <u>Wright</u>, Respondent argues that mere testing for a vaccine condition is not considered a residual effect of the vaccine-related injury. <u>Wright v. Sec'y of Health & Hum.</u>

<u>Servs.</u>, 22 F.4th 999, 1006 (Fed Cir. 2022). The context of the Federal Circuit's holding in <u>Wright</u>, however, was case specific and related to whether Petitioner had met the severity requirement of the Act to justify an award for compensation. Here, the question is the value of Petitioner's pain and suffering. There is no question that Petitioner here experienced her vaccine-related injury far longer than six months. Further, in <u>Wright</u>, there was no assertion based on the residual effect of anxiety, whereas here there is such a claim supported by a diagnosis of anxiety necessitating medical treatment.

The undersigned awards \$180,000.00 for Petitioner's pain and suffering. This award acknowledges the severity and refractory nature of her illness for two years, the following two year period that required continuing treatment which led to remission, and the emotional distress and anxiety she has experienced since the onset of her illness in 2016. In determining an award in this case, the undersigned does not rely on a single decision or case. Rather, the undersigned has reviewed the particular facts and circumstances in this case, giving due consideration to the circumstances and damages in other cases cited by the parties and other relevant cases, as well as her knowledge and experience adjudicating similar cases.

B. Lost Wages

Pursuant to the Vaccine Act, a petitioner may also recover "compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections" when their "earning capacity is or has been impaired by reason of [their] vaccine-related injury for which compensation is to be awarded." § 15(a)(3)(A).

1. Past Lost Wages

Petitioner was a part-time preschool teacher when she received the vaccination at issue and developed ITP. As explained in her declarations, she continued to work after she was diagnosed with ITP, and until the COVID pandemic began in March 2020, when she stopped working due to anxiety and stress about becoming ill. She returned to the preschool in October 2022, but took reduced hours, only working 1.5 hours instead of 4 hours per day for five days per week.

There is no foundational evidence to show that Petitioner experienced a reduction or loss of wages from the date of her diagnosis in 2016, until Petitioner quit working due to the COVID pandemic in 2020.

Petitioner contends that from the date of her vaccine injury in 2016 to the date of her economist's report in 2023, the present value of her lost earnings was \$14,994.00. Pet. Br. at 25 (citing Pet. Ex. 52 at 4-6, 10-14). Respondent's calculation for past lost earnings is \$14,694.00, which covers September 2020 through the 2023-2024 school year. Resp. Br. at 11-12 (citing Resp. Ex. DD at 4, 13).

The undersigned finds that from October 2016 until March 2020, Petitioner continued to work and did not experience a loss of wages. The undersigned awards compensation for a loss of wages from March 2020 (or September 2020 if Petitioner was compensated by her employer

for the remainder of the 2019-2020 school year), until the period reflected by the date of the filing of this Ruling, based on the calculations performed by Respondent's expert, Dr. Kennedy, using the same foundational information and appropriate adjustments for taxes, discount rate, etc. as cited in his expert report, updated to reflect the current date. See Resp. Ex. DD at 4.

2. Future Lost Wages

Petitioner seeks lost earnings of \$266,275.00 from 2023 to 2047. Pet. Br. at 26. Respondent contends that Petitioner has not proven she is entitled to future lost wages. The undersigned finds that Petitioner is entitled to future lost wages based on the opinions of Dr. Ghose.

Dr. Ghose has opined that Petitioner has an autoimmune illness which contributes to fatigue, insomnia, and joint discomfort, which are caused by her chronic ITP. He opined that Petitioner is expected to miss time from work, and that she has physical limitations ("standing, sitting, lifting, carrying, bending, kneeling[,] and frequently changing positions"). Pet. Ex. 43 at 4. He further opined that she can work, but that she should continue her current part-time position. Additionally, Petitioner will leave the work force earlier than average due to her illness, according to Dr. Ghose.

Dr. Ghose cited two studies about patients, like Petitioner, who had sustained remissions after treatment with thrombopoietin receptor agonists such as Promacta. See Pet. Ex. 44 at 2, 4 (noting 28 out of 54 patients had complete remission after treatment, and eight patients had a sustained response after treatment was withdrawn);²² Pet. Ex. 45 at 1 ("Of the 49 evaluable patients, 26 patients showed sustained response after discontinuing eltrombopag without additional ITP therapy Platelet response following eltrombopag cessation may be sustained in an important percentage of adult primary ITP patients who achieved [complete response] with eltrombopag.").²³ No predictive factors for relapse were identified in either study. Follow up in the first study was 5-27 months and 6-25 months in the second study. Pet. Ex. 44 at 2; Pet. Ex. 45 at 1.

Respondent's expert, Dr. Kreuziger, noted Petitioner's medical records do not consistently document fatigue or other symptoms that warrant a finding that she is unable to work full-time. Specifically, she cited Dr. Gorsuch's records in 2022 and 2023, documenting Petitioner's performance status as 0, defined as "fully active, able to carry on all pre-disease performance without restriction." Resp. Ex. CC at 3 (citing Pet. Ex. 37 at 7, 9; Pet. Ex. 41 at 7-8). Dr. Gorsuch also documented that Petitioner was asymptomatic. Pet. Ex. 37 at 5; Pet. Ex. 41

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²² Matthieu Mahévas et al., <u>The Temporary Use of Thrombopoietin-Receptor Agonists May Induce a Prolonged Remission in Adult Chronic Immune Thrombocytopenia. Results of French Observational Study</u>, 158 Brit. J. Haematology 865 (2014).

²³ Tomás José González-López et al., <u>Successful Discontinuation of Eltrombopag After Complete Remission in Patients with Primary Immune Thrombocytopenia</u>, 90 Am. J. Hematology E40 (2015).

at 6. Additionally, Ms. Becker, in 2024, documented a review of systems in which Petitioner denied fatigue. Resp. Ex. CC at 3 (citing Pet. Ex. 40 at 5-6).

Generally, the references in Petitioner's medical records to fatigue relate back to the diagnosis of her ITP in December 2016 and during the period of early treatment in February 2017. See Pet. Ex. 4 at 56-57. Otherwise, references to fatigue are contained in Petitioner's affidavit/declarations.

Therefore, Dr. Kreuziger is correct to say that the medical records do not consistently report fatigue. However, Petitioner asserts that she does have fatigue. And Dr. Ghose explained fatigue and other physical limitations can occur in chronic ITP, which would prevent Petitioner from working full-time. He also opined that she should continue to work at her current level of 7.5 hours per week. Thus, while this is a close call, the undersigned finds that Petitioner has presented evidence to support a finding that her fatigue limits her from working full-time.

Next, the evidence establishes that Petitioner has not previously worked full-time but has always held part-time employment so that she could care for her daughter. Once her daughter went to high school, she planned to seek more full-time work. That plan, however, relates to future events. Moreover, Petitioner has not worked full time in a number of years, and has not presented any evidence of full time employment in the past. Therefore, the undersigned finds it is speculative to assume that Petitioner would return to full time employment in the future if she had not developed ITP.

Compensation awarded for a petitioner's anticipated loss of earnings may not be based on speculation. See, e.g., J.T. v. Sec'y of Health & Hum. Servs., No. 12-618V, 2015 WL 5954352, at *7 (Fed. Cl. Spec. Mstr. Sept. 17, 2015) (indicating §15(a)(3)(A) "does not envision that 'anticipated loss of earnings' includes speculation" and thus refusing to allow lost wages on a planned business venture that was too indefinite), mot. for rev. den'd, 125 Fed. Cl. 164 (2016). Basing claims of future wages on a petitioner's own expectancies that differ from the generally accepted work life expectancy of an individual would likely be speculative, and not calculated in a "cautious manner." Brown v. Sec'y of Health & Hum. Servs., No. 00-0182V, 2005 WL 2659073, at *6 (Fed. Cl. Spec. Mstr. Sept. 21, 2005).

The undersigned finds that based on the Petitioner's prior work record, her medical records, the expert reports, and the medical literature, there is preponderant evidence to establish that Petitioner would have continued to work part-time, 20 hours per week during the school year from August until the following May, each year until the age of retirement, if she had not developed ITP. The evidence also establishes that the Petitioner can and does work 7.5 hours per week during the school year. Petitioner has not shown by preponderant evidence that she would have become employed full-time in the future.

In summary, the undersigned finds that Petitioner is entitled to future lost earnings, for part-time employment of 20 hours per week less 7.5 hours (reflecting her current work schedule), for a nine month school year, based on her current employment. The appropriate adjustments for taxes, net discount rate, and work life expectancy shall be considered, and further the

calculations shall be "in accordance with generally recognized actuarial principles and projections." § 15(a)(3)(A).

C. Unreimbursable Expenses

The Vaccine Act further permits a Petitioner to recover "actual unreimbursable expenses incurred before the date of judgment," including those that "(i) resulted from the vaccine-related injury for which [P]etitioner seeks compensation, (ii) were incurred by or on behalf of the person who suffered such injury, and (iii) were for diagnosis, medical or other remedial care, rehabilitation . . . determined to be reasonably necessary." § 15(a)(1)(B).

Here, the parties do not dispute Petitioner's request for unreimbursable expenses. Therefore, Petitioner shall be awarded \$7,676.42 for past unreimbursed expenses.

VI. CONCLUSION

In determining an award in this case, the undersigned does not rely on a single decision or case. Rather, the undersigned has reviewed the particular facts and circumstances in this case, giving due consideration to the circumstances and damages in other cases cited by the parties and other relevant cases, as well as her knowledge and experience adjudicating similar cases.

The undersigned finds that Petitioner shall be awarded (1) \$180,000.00 for pain and suffering and (2) \$7,676.42 for past unreimbursed expenses.

Regarding lost earnings, the parties' expert economists shall calculate the lost wages in accordance with the undersigned findings herein. The parties shall endeavor to come to an agreement as to the proper calculation including the appropriate discount rate. If the parties are unable to do so, the undersigned will resolve the dispute.

A joint status report shall be filed in <u>30 days</u>, not later than Friday, March 28, 2025, reporting the lost earnings calculation reached by the parties. If an agreement is not reached, the status report shall be accompanied by brief letters from the parties' respective experts stating their calculations as well as any disagreement that they have with the opposing expert's calculation.

Once all items of damages have been resolved, a Damages Decision will issue with the final award for compensation.

IT IS SO ORDERED.

s/Nora Beth DorseyNora Beth DorseySpecial Master